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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,204

05/04/2007

Simon Bates

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22852

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07/25/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

KILPATRICK, BRYAN T

ART UNIT

PAPER NUMBER

4112

MAIL DATE

DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,204	Applicant(s) BATES ET AL.	
	Examiner BRYAN T. KILPATRICK	Art Unit 4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/04/2007, 08/08/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office action based on the application *10/590,204* filed *February 24, 2005*; claims priority to application *60/546,976* filed *February 24, 2004*.
2. Claims *1-14* are pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent Application Publication 2004/0103130 (IVANISEVIC et al.) in view of “Improved measures of quality for the atomic pair distribution function,” *J. Appl. Cryst.* 36, pp. 53-64 (PETERSON et al.).

Instant claim 1 requires a method comprised of providing a first and second sample PDF trace of a substance, comparison of the PDF traces to determine whether the substances of the samples have the same or different solid forms. IVANISEVIC et al. discloses in claim 1 a method of analyzing diffraction patterns comprised of receiving up to three diffraction patterns and determining similarities between them. IVANISEVIC et al. also discloses that diffraction can be used to determine if variations in solid forms are present in solids in paragraph [0003] of the Background Section. IVANISEVIC et al. does not appear to explicitly disclose the use of atomic pair distribution function, “PDF”, for analysis of solid forms. However, PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations. IVANISEVIC et al. and PETERSON et al. are analogous art because they are from the same field of endeavor of analyzing solid forms of substances. At the time of the invention, it would have been obvious to one of ordinary skill in the art to use the diffraction patterns of IVANISEVIC et al. with the computations of PETERSON et al. to produce PDF data to analyze solid forms. The motivation would have been to improve the processing of the data collected by x-ray diffraction, as stated in the first

paragraph of the Introduction Section of PETERSON et al. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Instant claim 2 requires the substance being analyzed is a chemical compound. IVANISEVIC et al. discloses in paragraph [0003] the invention can be used to identify new solid forms of compounds and elements.

Instant claim 3 requires the substance is a pharmaceutical compound. IVANISEVIC et al. discloses in paragraph [0060] that the invention can be used to identify solid forms of drugs, a material made of pharmaceutical compounds.

Instant claim 4 requires the pharmaceutical compound is a pharmaceutically acceptable salt. Paragraph [0003] in the Background Section of IVANISEVIC et al. discloses the analysis of salts.

Instant claim 5 requires the substance is a mixture of two or more chemical compounds. Instant claim 6 requires the substance is a cocrystal. Instant claim 7 requires a compound in the mixture is water and the substance is a hydrate. Paragraph [0061] in IVANISEVIC et al. discloses a variety of crystalline sample materials that encompass the limitations of instant claims 5-7.

Instant claim 8 requires the analysis of a substance of at least one sample that is a disordered crystalline and the PDF comparison method of the instant application. In IVANISEVIC et al., paragraph [0061] discloses a variety of crystalline sample materials and pages 8-9 discloses a method for analysis involving disorder, and PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations.

Instant claim 9 requires the solid form of a substance of the first or second sample is a known solid form of the substance. IVANISEVIC et al. discloses in claim 1 a method of analyzing diffraction patterns comprised of receiving up to three diffraction patterns and determining similarities between them.

IVANISEVIC et al. also discloses that diffraction can be used to determine if variations in solid forms are present in solids in paragraph [0003] of the Background Section. PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations. The combination of the arts from IVANISEVIC et al. and PETERSON et al. would be indiscriminant of whether the solid forms are known or unknown.

Instant claim 10 requires at least one of the PDF traces is calculated from a composite x-ray powder diffraction pattern derived from two or more measured x-

ray powder diffraction patterns of the sample. PETERSON et al. discloses on page 54 in the first full paragraph a technique of combining multiple diffraction patterns for analysis.

Instant claim 11 requires a method of screening new solid forms of a substance comprised of providing a PDF trace of each of a plurality of test samples of a substance, one or more PDF traces of known solid forms of the substance, and comparing the PDF traces of one or more of the test samples to one or more of the PDF traces of known solid forms to identify any substances in the test samples that have a new solid form. IVANISEVIC et al. discloses in claim 1 a method of analyzing diffraction patterns comprised of receiving up to three diffraction patterns and determining similarities between them. IVANISEVIC et al. also discloses that diffraction can be used to determine if variations in solid forms are present in solids in paragraph [0003] of the Background Section. PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations. The combination of the arts from IVANISEVIC et al. and PETERSON et al. would be indiscriminant of whether the solid forms are known or unknown.

Instant claim 12 requires a method comprised of providing a PDF trace of each of a plurality of test samples of a substance, and grouping the plurality of PDF traces of the substance by similarity into two or more groups through hierarchical

cluster analysis. IVANISEVIC et al. initially discloses in the Abstract and Summary Section on pages 1-2 methods of analyzing using diffraction patterns that can come from an x-ray diffraction technique and then using hierarchical cluster analysis. PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations.

Instant claim 13 requires a system comprised of a means for providing a PDF trace of a first and second sample of a substance, and a means for comparing the PDF traces to determine whether the first and second substances of the sample have the same or different solid forms. IVANISEVIC et al. discloses in claim 48 a system that collects diffraction patterns, and then compares diffraction patterns for similarities. IVANISEVIC et al. also discloses that diffraction can be used to determine if variations in solid forms are present in solids in paragraph [0003] of the Background Section. PETERSON et al. discloses in the Introduction Section on pages 53-54 that PDF data can be produced using x-ray diffraction data in conjunction with calculations.

Instant claim 14 requires the use of a computer-readable medium. Paragraph [0143] of IVANISEVIC et al. discloses the use computer-readable media.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. W.O. 2004/013622 AI discloses the same invention as U. S. 2004/0103130 (IVANISEVIC et al.).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Mon - Fri (alt Fri off); 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128